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| 10/560,289 | 05/26/2006 | Robert J Benkowski | 021906-024US | 3187 |
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| EXAMINER LAVERT, NICOLE F | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

hoip@lockelord.com

Office Action Summary

Application No.

10/560,289

Applicant(s)

BENKOWSKI ET AL.

Examiner

NICOLE F. LAVERT

Art Unit

3762

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-31 is/are rejected.
- 7) ☒ Claim(s) 20-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/30/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 October 2010 has been entered.

Drawings

1. The drawings are objected to because the current drawings are not clear and concise and new clearer drawings are required. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not

accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required, i.e. the abstract submitted on 12 December 2005 is a copy of the WIPO publication and is not on a separate sheet. Correction is required.

The disclosure is also objected to because of the following informalities: Any application numbers listed in the disclosure should be updated to reflect their patent status (e.g. pending, patented, abandoned) and publication numbers should be provided for any applications that have been published. Specifically, pp 7, lines 9-12 of the disclosure requires correction. Furthermore, any reference to attorney docket numbers appearing therein should be removed.

3. The use of the trademark “DeBakey VAD” has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

4. Claims 20-31 are objected to because of the following informalities:

Claim 20 recites the limitation "the time domain" in lines 4 & 8. There is insufficient antecedent basis for this limitation in the claim.

In regards to claim 20, the claim limitation "...frequency domain..." is inferentially included and it is unclear if the above limitation is being positively or functionally recited

In regards to claim 23, the claim limitations "...upper boundary...lower boundary conditions..." are inferentially included and it is unclear if the above limitations are being positively or functionally recited.

Claim 24 recites the limitation "the desired control mode" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 recites the limitation "the event" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "the real-time flow waveform" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 recites the limitation "the group comprising" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 20 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent No. 7,396,327. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are directed to obvious variations of controlling a blood pump by analyzing a flow waveform or signal in both a time and a frequency domain.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 20, 22 & 29** are rejected under 35 U.S.C. 102(b) as being anticipated by Nazarian et al. (US 5,368,554).

Nazarian et al. discloses a method of controlling a blood pump (e.g., col 2, ln 26-44) comprising: receiving, in a controller (e.g., via the disclosed microprocessor 100 of the flowmeter 60), a flow signal from an implanted flow signal (e.g., via the disclosed flow sensor 61), the flow signal indicative of an instantaneous flow waveform [e.g., (col 3, ln 53-60) & (Fig 1)]; analyzing, in the controller, the flow waveform in the time domain; analyzing, in the controller, the flow waveform in frequency domain; and outputting, from the controller, a control signal to control an implanted blood pump in response to the analysis of the flow waveform in the time and frequency domains [e.g., (col 3, ln 53-60), (col 4, ln 17-40 & 66-68)-(col 5, ln 1-8), (col 8, ln 3-68) & (Fig 4)].

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 21, 23-25 & 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nazarian et al. (US 5,368,554) in view of Hertz et al. (US 6,090,048).

Nazarian et al. discloses the claimed invention having a method of controlling a blood pump via an analysis means in the form of a controller, except wherein said analysis of a flow waveform determines a suction boundary. Hertz et al. teaches that it is known to use a method that determines boundary conditions associated with a blood pumping device, such as conditions concerning for suction, maximum speed, minimum speed, and minimum flow (e.g., col 6, ln 5-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Nazarian et al. with the method that determines boundary conditions such as suction, maximum speed, minimum speed, and minimum flow as taught by Hertz et al. since such a modification would provide the method having the means of analyzing a flow waveform so as to determine a suction boundary for providing the predictable results pertaining to efficiently detecting the condition of a blood vessel via a safe and reliable means that provides information regarding the effectiveness of the device used (e.g., Hertz, col 6, ln 5-25).

11. **Claims 26-28 & 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nazarian et al. (US 5,368,554) in view of Benkowski et al. (US 6,183,412).

Nazarian et al. discloses the claimed invention having a method of controlling a blood pump except wherein said method further utilizes a fail-safe feature and/or an alternative control mode in order to switch to a Constant Speed mode. Benkowski et al. teaches a safety feature in the form of a switching device (e.g., element 90) that monitors the controlling device of a blood pump and control the operation of said blood pump [e.g., (col 6, ln 52-67)-(col 7, ln 1-11) & (Fig 3)]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Nazarian et al. with utilizing the safety, switching device as taught by Benkowski et al., since such a modification would provide the method that utilizes a fail-safe feature and/or an alternative control mode in order to switch to a Constant Speed mode for providing the predictable results pertaining to utilizing an additional means to control the operations of a blood pump so as to maintain a speed previously determined to be safe [e.g., (col 6, ln 52-67)-(col 7, ln 1-11) & (Fig 3)].

Response to Arguments

12. Applicant's arguments filed 12 October 2010 have been fully considered but they are not persuasive. The previous double patenting rejections are still pending due to the applicant not properly responding to the double patenting rejection, i.e. a terminal disclaimer in response to the last office action sent out on 19 August 2010 has not been submitted by the applicant.

13. Applicant's arguments with respect to claims 20-31 have been considered but are moot in view of the new ground(s) of rejection. See the above action

14. Applicant's arguments, filed 12 October 2010, with respect to the 101 and 112, first paragraph claim rejections have been fully considered and are persuasive and have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole F. LaVert/
Examiner, Art Unit 3762